Section 1.0
510(k) Summary
as required by section 807.92(c)

maxMorespine Endoscope

OCT - 9 2009

1.1 Submitter Information

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Contact Information
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1.2 Establishment / Owner Information

Hoogland Spine Products GmbH
Feringastr. 7a
D-85774 Unterföhring - Germany

FDA Establishment Registration Number
30065611611

1.3 Proprietary Name

maxMorespine Endoscope
TOM Endoscope

1.4 Common Name

Spinal Endoscope

1.5 Classification Name

Arthroscope and accessories

1.6 Regulation Number

21 CFR 888.1100

1.7 Regulatory Class
Class II

1.8 Classification Product Code
HRX

1.9 Intended Use
The maxMorespine Endoscope when used with recommended third party accessories/components, is intended to visualize the inside of the patient through a cannulated incision for diagnostic and surgical procedures, such as arthroplasty, nucleotomy, discectomy and foraminotomy.

1.10 Device Description / Technology Characteristics
The maxMorespine Endoscope is a rigid, multi-channel endoscope comprised of a working channel, rod lens optical system to transmit light and images with irrigation channel(s) and stopcocks. The body is designed of an outer and inner tube of surgical grade stainless steel. The proximal end of the endoscope; eyepiece and light post is adaptable to industry standard endoscopic camera and light systems. The endoscope will be introduced into the patient via a minimally invasive access through a working cannula with various instruments introduced through the Endoscope working channel (maxMorespine System submitted sepatately - K090132).

1.11 Substantial Equivalence
The maxMorespine TOM Endoscope is substantially equivalent in purpose, design, materials and function to the following marketed products;

- Joimax THESSYS Multiscope (K051827)
- RIchard Wolf Yeung Endoscopic Spine System (K973405)
- Arthro Kinetics' Endoscopic Spine System (K061246)

1.12 Sterilization
maxMorespine Endoscopes will be sold non-sterile, to be sterilized prior to each procedure by the user. Sterilization instructions are provided in the Instructions for Use (see Section 2.4)

1.13 Software
No Software is needed for the maxMorespine Endoscope

1.14 Conclusion
The specifications and intended use of the maxMorespine Endoscope is the same as those of the claimed predicate devices. There are no significant differences in design or manufacturing materials between the maxMorespine Endoscope and predicate devices. In all aspects, the maxMorespine Endoscope is substantially equivalent to products actively marketed as demonstrated in Predicate Devices Comparison Chart (see section 4.1)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Hoogland Spine Products GmbH
% Spine Now, LLC
Ms. Joan L. Carter
94 Gardiners Avenue #307
Levittown, New York 11756

OCT - 9 2009

Re: K083552
Trade/Device Name: maxMorespine Endoscope
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: October 2, 2009
Received: October 5, 2009

Dear Ms. Carter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number; K083552

Device Name: maxMorespine Endoscope

Indications for Use:

The maxMorespine Endoscope when used with recommended third party accessories/components, is intended to visualize the inside of the patient through a cannulated incision for diagnostic and surgical procedures, such as arthroplasty, nucleotomy, discectomy and foraminotomy.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083552